UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,426	04/24/2001	Jonathan W. Nyce	EPI-00311	5444

26380 7590 04/09/2002

EPIGENESIS PHARMACEUTICALS
7 CLARK DRIVE
CANBURY, NJ 08520

EXAMINER	
JIANG, SHAOJIA A	

ART UNIT	PAPER NUMBER
1617	6

DATE MAILED: 04/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/841,426	NYCE, JONATHAN W.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-79* is/are pending in the application.

4a) Of the above claim(s) *49-79* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's preliminary amendment in response to the Restriction Requirement in Paper No. 5, submitted February 20, 2002 is acknowledged. Currently, claims 1-79 are pending in this application.

Election/Restrictions

Applicant's election with traverse of the invention of Group I, Claims 1 (in part), 7-14, and 15-48 (in part) in Paper No. 5, submitted February 20, 2002 is acknowledged. Applicant's amendment (amending claim 1) has been considered and found persuasive as to the restriction between Groups I-II; and Groups III-IV. Therefore, the Requirement for Restriction is modified as to that the invention of Group I is herein combined with the invention of Group II and the invention of Group III is herein combined with the invention of Group IV. However, the invention of Group I-II is independent and distinct from Groups III-IV since Group I-II is drawn to drawn to pharmaceutical compositions and a kit herein, whereas Inventions of Group III-IV is drawn to an in vivo method of preventing or treating a disorder or condition associated with abnormal levels of adenosine and other conditions herein. Inventions Group I-II; and III-IV are independent and distinct each from other since they are related as product and process of use as discussed in the Requirement for Restriction and an undue burden on the Office is seen for the search all inventions herein, as discussed in the Requirement for Restriction. Note that the search is not limited to patent files. Note that the search field for a composition or kit employing a composition is different from the search field for a specified method of use employing the same a composition.

Therefore, Applicant's election of Group I will be taken an election of the invention of Groups I-II, claims 1-15 and 17-48 herein, and claims 16 and 49-79 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. The requirement between Groups I-II; and Group III-IV is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-6, 17, 19-28 and 32-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "active agent " in claims 5-6 renders the claim indefinite. The expression " active agent " is unclear as to which active agent in the composition herein.

The expression " other therapeutic agents" in claim 17 renders claims 17 indefinite as failing to clearly set forth the metes and bounds of the patent protection desired. Therefore, the scope of claims is indefinite as to the composition encompassed thereby.

Claims 19-28 and 32-41 recite the limitation "the formulation". There is insufficient antecedent basis for this limitation in the claim since claim 18 is drawn to a composition.

Claims 42-48 recite the limitation "the kit". There is insufficient antecedent basis for this limitation in the claim since claim 16 is drawn to the method and claim 15 is drawn to the composition.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 and 17-48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-19 of U.S. Patent No. 5,527,789 (PTO-892).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent are drawn to a pharmaceutical composition comprising the dehydroepiandeosterone and ubiquinone with n being from 1 to 10, 6 to 10, or 10, and pharmaceutically acceptable carrier such as an aqueous or a solid carrier. The claim of the instant application is drawn to a pharmaceutical composition or formulation, or kit comprising the same dehydroepiandeosterone and ubiquinone with n

being from 1 to 12, 1 to 10, 6 to 10, or 10, in the effective amounts of about 0.1 to about 40% or about 1 to about 20% w/w, and pharmaceutically acceptable carrier such as an aqueous or a solid carrier, and this pharmaceutical composition or formulation, or kit may be further comprises other agents such as preservatives, antioxidants flavaoring agents, volatile oils, buffering agents, dispersants or surfactants.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the effective amounts of about 0.1 to about 40% or about 1 to about 20% w/w of active compounds herein in a pharmaceutical composition, formulation, or kit since such active compounds are known to be useful in a pharmaceutical composition. The range of effective amounts of about 0.1 to about 40% or about 1 to about 20% w/w is considered a broad range. Additionally, one of ordinary skill in the art would have been motivated to optimize the effective amounts of active ingredients in the composition because the optimization of amounts of active agents to be administered is considered well within the skill of artisan in the competence level of an ordinary skilled artisan in pharmaceutical science.

Further, one of ordinary skill in the art would have been motivated to employ other well known agents such as preservatives, antioxidants flavaoring agents, volatile oils, buffering agents, dispersants or surfactants in a composition since ubiquinones herein are well known antioxidants, coenzyme Q10, and the employment of well known pharmaceutically acceptable agents in a composition is considered well within the skill of artisan in pharmaceutical science, involving merely routine skill in the art.

Therefore, the claimed invention in claims 1-15 and 17-48 is clearly seen to be obviousness-type double patenting over claims 13-19 of U.S. Patent No. 5,527,789.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-15 and 17-48 rejected under 35 U.S.C. 103(a) as being unpatentable over Prendergast (4,956,355 PTO-892).

Prendergast discloses that particular dehydroepiandrosterones (DHEA) herein are useful in a pharmaceutical composition or a pharmaceutical formulation of enteral, parental, injectable, or topical administration. See abstract, col.1 lines 36-57, col. 4-5 and claim 6. Prendergast also discloses the effective amounts of dehydroepiandrosterones in the composition and other agents and pharmaceutically acceptable excipients within the instant claim in the compositions therein (col.5).

Prendergast does not expressly disclose that the range of effective amounts is about 0.1 to about 40% or about 1 to about 20% w/w. Prendergast does not expressly disclose that the composition optionally further comprises the particular antioxidant herein, ubiquinone.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to optionally further employ the particular antioxidant herein, ubiquinone, in the composition of Prendergast and optimize the effective amounts of active ingredients in the composition.

One having ordinary skill in the art at the time the invention was made would have been motivated to optimize the effective amounts of active ingredients in the composition of Prendergast since the effective amounts of particular DHEAs in the composition to be administered are known according to Prendergast, and the range of effective amounts of about 0.1 to about 40% or about 1 to about 20% w/w is considered a broad range. Moreover, the optimization of amounts of active agents to be administered is considered well within the skill of artisan in the competence level of an ordinary skilled artisan in pharmaceutical science.

One having ordinary skill in the art at the time the invention was made would have been motivated to optionally further employ the particular antioxidant herein, ubiquinone, in the composition of Prendergast since ubiquinones herein are well known antioxidants, coenzyme Q10, and adding a well known antioxidant to a composition is considered well within the skill of artisan in pharmaceutical science, involving merely routine skill in the art.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
April 4, 2002

MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600